



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 73

[Docket No. FDA-2014-C-1552]

Colorcon, Inc.; Filing of Color Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of petition.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that we have filed a petition, submitted by Colorcon, Inc., proposing that the color additive regulations be amended to provide for the safe use of spirulina extract as a color additive in coating formulations applied to dietary supplement and drug tablets and capsules.

DATES: The color additive petition was filed on September 22, 2014.

FOR FURTHER INFORMATION CONTACT: Molly A. Harry, Center for Food Safety and Applied Nutrition (HFS-265), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740-3835, 240-402-1075.

SUPPLEMENTARY INFORMATION: Under section 721(d)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379e(d)(1)), we are giving notice that we have filed a color additive petition (CAP 4C0300), submitted by Colorcon, Inc., 275 Ruth Rd., Harleysville, PA 19438. The petition proposes to amend the color additive regulations in 21 CFR part 73 Listing of Color Additives Exempt From Certification to provide for the safe use of spirulina extract as a color additive in coating formulations applied to dietary supplement and drug tablets and capsules.

We have determined under 21 CFR 25.32(r) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Dated: October 16, 2014.

Dennis M. Keefe,

Director,

Office of Food Additive Safety,

Center for Food Safety and Applied Nutrition.

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